Carolyn P. Daurio, MS, MBA
Technical Director, Regulatory Affairs
Pharmaceutical Research & Development
Mail Stop: ISF-445
Tel: 732.729-5549
Fax: 732.729-5625

2100 Ronson Road
Iselin, NJ 08830-3077
Tel: 732.855.3800
Fax: 732.855.9366

30 March 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. 98D-0994

Following please find comments to the Draft Guidance for Industry entitled "BACPAC I: Intermediates in Drug Substance Synthesis; Bulk Actives Postapproval Changes: Chemistry, Manufacturing, and Controls Documentation," published in the Federal Register, Volume 63, Number 229, on November 30, 1998.

As requested, specific comments are identified to line number.

Section A. Equivalence of Impurity Profiles

Line 132. We suggest that for an intermediate, the guidance be revised to "no new impurity is observed at or above 0.1 percent **(or 0.2 percent for an intermediate with only veterinary use)**".

The reason for this is so that the threshold is the same as that for a drug substance for veterinary products, which is described in the guidance for industry on Impurities in New Veterinary Medicinal Products (VICH GL10, 22 October 1998, for consultation at Step 4 - Draft 1).

Thank you for your consideration.

Sincerely,

Carolyn P. Daurio

Carolyn P. Daurio

98D-0994

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SPH43

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